REMARKS

This Amendment is in response to the Office Action mailed December 28, 2007. No claims are amended. Accordingly, Claims 11 and 14-23 remain pending. Reconsideration is respectfully requested.

Summary of the Invention

The present invention describes binary, single phase titanium-zirconium alloys (TiZr) which have a Zr content of more 10% to less 19% by weight, 0.1% to 0.3% by weight oxygen and not more than 1 % by weight of additional strength enhancing additives and technical impurities. The alloys are further characterized in that they are obtainable by a process comprising hot forging above α/β phase transition and rapid cooling and subsequent cold processing of said alloy. It is also important to note that tensile strength is only one among several important factors which is critical for TiZr-alloys used for the production of surgical implants.

Claim Rejections

Claims 11, 14-15, 17-19 and 21-23 stand rejected under 35 U.S.C. §103(a) as being obvious in view of GB 1,305,879 (GB `879). The examiner asserts that GB `879 broadly teaches a titanium alloy suitable for medical implants with a preferred range of 25-75% Zr. The examiner further asserts that preferred embodiments do not constitute a teaching away from a broader disclosure. Applicants respectfully traverse.

The argument put forth by the examiner assumes that the range of Zr in a surgical implant claimed by applicants, i.e., more than 10% but less than 19% by weight, is disclosed by GB `879. However, it is not. All that is disclosed in GB `879 is a table properties "which are important in regard to use as an implant." GB `879 then goes on to explain why one would not want to have a

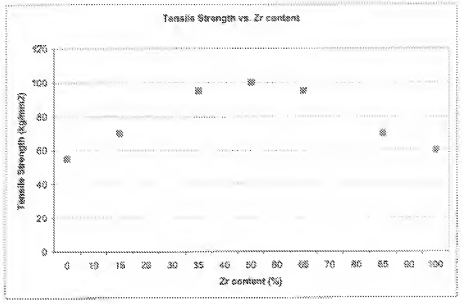
Zr content as low as that claimed by applicants. Thus, there is no disclosure of an alloy for use in a surgical implant having the claimed Zr content.

The principal components of the alloy disclosed in GB `879 are the Zr content which is in the range of 25% to 75% weight, and Ti making up the remainder together with at most 3% of other elements. An implant must have a suitable strength in order to prevent breaking. Not all TiZr alloys disclosed show the necessary strength which renders them suitable as implant materials. This strength should be in the range of 780 to 880 MPa. Therefore, a skilled person would use alloys having a Zr content which is higher than 35% by weight where he knows that the strength is sufficiently high for implants.

GB `879 teaches that the tensile strength of TiZr-alloys increases with an increasing Zr-content up to a Zr-content of 50% by weight. However, tensile strength then decreases again. Thus one skilled in the art would tend to choose TiZr-alloy having 50% by weight Zr in order to maximize the tensile strength.

GB `879 does not describe the combination of tensile strength, elongation at break and stress at break a TiZr-alloy must have in order to achieve a risk of failure (which means breaking) which is as low as the risk of failure of TiZr alloys according to the present invention.

The examiner also asserts on page 3 of the Office Action that GB `879 "teaches that the amount of added Zr is directly related to the strength achieved, and therefore is a result effective variable (wherein the expected result is increase in strength and decrease in elongation with increasing amounts of Zr, see Table p2)." To the contrary, GB `879 discloses a maximum tensile strength at a Zr content of 50%, the tensile strength subsequently decreasing with a further increase in Zr content. Further, the elongation decreases to a minimum at a Zr content of 50% and then increases again as the Zr content further increases to 100%.



While tensile strength increases with an increasing Zr-content up to 50% Zr and then decreases again, it has been discovered by applicants that a maximized tensile strength is disadvantageous for surgical implants, particularly when used in the dental field. Stress at break is a measure for the toughness of a metal (see specification page 8, first paragraph). It was recognized by applicants that TiZr-alloys having an elongation at break between 18.1% and 10.9% and, as a further factor, a stress at break in the range of 1436 MPa and 1454 MPa show a much lower risk of failure. At a Zr-content of 25.6% by weight, the elongation at break drops below 10% (page 6, table 1 of the specification). An elongation at break below 10% renders TiZr-alloys highly unsuitable for the production of surgical implants. Thus, elongation at break and stress at break are additional result-effective parameters and must be considered in combination with the tensile strength of the TiZr alloys.

The examiner acknowledges in the Office Action that particularly claimed ranges can support the patentability of the subject matter if it is shown that the particular parameter

produces new and unexpected results. Applicants respectfully assert that the portions of the specification cited above do, in fact, demonstrate the unexpectedly good results achieved with the alloy of the invention.

Biocompatibility can be assessed in cell culture experiments. With regard to hard tissue, experiments with osteoblast cells are of interest. It has been shown that TiZr-alloys according to the present invention do not cause any retardation in the growth of cultured osteoblasts (specification page 9, table 5).

Therefore, applicants respectfully assert that the claims are not obvious in view of GB `879. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 11 and 14-23 stand rejected under 35 U.S.C. §103(a) as being obvious in view of GB `879 in further view of Chem. Ab. No. 103239 (CA `239) and U.S. 5,169,597 issued to Davidson. The examiner acknowledges that GB `879 does not disclose the claimed hot forging temperature range or rapidly cooling after hot forging. The examiner relies upon CA`239 for the disclosure of the hot forging temperature. Davidson is relied upon for the element of rapidly cooling after hot forging.

CA`239 describes alloys for implants containing titanium and 5 to 20 mass% Zr. Further elements of the alloy are Sn, Nb, Ta and Pd. The alloys disclosed are binary TiZr-alloys having an α and a β phase. Nb and Ta are known to stabilize the β-phase. Thus, a skilled person would expect to end up with a dual phase alloy. However, dual phase alloys are disadvantageous because their structure is inhomogeneous which makes it very difficult to achieve a desired surface topography in subsequent processing. Looking for suitable single phase titanium alloys and having the aforementioned in mind, CA`239 would lead a skilled person away from a solution.

In addition, the components Sn, Nb and Ta described in CA`239 have been shown to cause retardation in the growth of cultured osteoblasts (see page specification of the present invention page 9, table 5). CA`239 indicates forging of the described TiZr-alloys in their alpha and alpha/beta region. However, since the alloys described in CA`239 contain significant amounts of further components (10-20% Sn, 4-8% Nb and 2-4% Ta), it is uncertain if the conditions indicated also apply to TiZr-alloys according to the present invention, which have no further components apart from oxygen and technical impurities, the amount of which is 1% by weight or less. CA`239 does not give any hint that the conditions are applicable to TiZr-alloys according to the present invention or in what way they have to be altered. Thus, one skilled in the art would have no motivation to combine the teachings of GB `879 and CA`239.

Davidson describes biocompatible titanium alloys comprising titanium, niobium and up to 20% by weight zirconium. Such alloys (ternary alloys) never have a single phase. The alloys described in Davidson inevitably have the disadvantages of a surface with an undesirable inhomogeneous structure preventing a good stabilization of an implant in its environment (e.g. bone). To reduce this disadvantage Davidson suggests further coating of implants with porous beads or wires of titanium alloy attached to the implant surface by sintering (Davidson, column 7, lines 9 to 16).

Further, Nb has been demonstrated to cause retardation in the growth of osteoblast cells which is disadvantageous for osteointegration (see page specification of the present invention page 9, table 5). The Examiner states that Davidson teaches rapid cooling after hot working of Ti-alloys thereby achieving a finer grain size and an adequate strength. However, Davidson describes ternary, dual phase alloys and fails to show that the conditions disclosed are also applicable to binary, single phase TiZr alloys according to the present invention. One skilled in the art does not get a hint in Davidson giving him reasonable expectation of success to do so.

Again, the Examiner combines single features without taking into account the whole teaching of the document. A prior art reference must be considered in its entirety, including those portions that would lead away from the claimed invention. MPEP § 2141.02.

Conclusion

Accordingly, Applicant respectfully submits that the application is now in proper form for allowance, which action is earnestly solicited. If resolution of any remaining issue is required prior to allowance of the application, it is respectfully requested that the Examiner contact Applicant's attorney at the telephone provided below.

Respectfully submitted,

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